



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/698,291

10/31/2003

Martin T. Gerber

P-9492.00US

1410

27581 7590 06/23/2008  
MEDTRONIC, INC.  
710 MEDTRONIC PARKWAY NE  
MINNEAPOLIS, MN 55432-9924

EXAMINER

MANUEL, GEORGE C

ART UNIT

PAPER NUMBER

3762

MAIL DATE

DELIVERY MODE

06/23/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/698,291	<b>Applicant(s)</b> GERBER ET AL.	
	<b>Examiner</b> George Manuel	<b>Art Unit</b> 3762	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 March 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5, 7-26 and 28-67 is/are pending in the application.  
     4a) Of the above claim(s) 64-67 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-26, 28-63 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

***Election/Restrictions***

Newly submitted claims 64-67 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: ring electrodes are patentably distinct from wire-like electrodes and a method of introducing a lead into an epidural space or proximate to a sacral foramen would require different fields of search from the originally claimed invention.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 64-67 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

***Response to Arguments***

Applicant's arguments filed 3/27/08 have been fully considered but they are not persuasive. The plurality of electrodes comprises 28B and 28C. In addition, a fixation mechanism that is axially displaced from the plurality of electrodes comprises 28A. Fallwell et al disclose a sheath serves to protect shaft portion 12 and in particular braided conductive member 28 during manipulation through the patient's vasculature. Clearly the sheath provides a restraint mechanism and upon removal permits the wire-like elements to expand.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1, 3, 8, 9, 11-15, 20, 21, 22, 24, 29, 32-36, 41, 42, 53, 55, 58, 59, 60 and 62 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Fallwell et al (US 7,255,695).

Fallwell et al disclose an embodiment in Fig. 14 that comprises a lead body having a proximal end 12 and a distal end 18. The examiner is interpreting 28B and 28C to comprise a plurality of stimulation electrodes and 28A to comprise a fixation mechanism. Col. 11, lines 63-63 teach the mapping and ablations sectors and/or wires may be activated independently, and may be activated concurrently.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2, 4, 5, 7, 10, 23, 25, 26, 28, 30, 31, 43-47, 52, 54, 56, 57, 61 and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fallwell et al (US 7,255,695).

Regarding claims 2, 4, 5, 23, 25, 26, 52, 54, 56, 57 and 61, one of ordinary skill in the art would have found it obvious to construct the wire-like elements of 28 with shape memory alloy, super-elastic material because Fallwell et al suggest the braided conductive member 28 may be fabricated of a material of sufficient flexural strength so that the tissue is preferentially conformed to match the expanded or partially expanded shape of the braided conductive member 28. In addition, Fallwell et al teach the filaments may be formed of Nitinol type wire.

Regarding claims 7, 10, 28, 31, 43 and 63, one of ordinary skill in the art would have found it obvious to construct the shaft portion 12 with a lumen to accommodate a stylet because a stylet is an art recognized actuating device and Fallwell et al suggest a thumb wheel (or any other suitable actuating device) may be connected to one or more pull wires which extend through shaft portion 12 and are connected to the distal end 18 of the catheter at an off-axis location.

Regarding claims 16-19, 37-40 and 48-51, one of ordinary skill in the art would have found it obvious to construct the fixation mechanism to have an expandable diameter in the range of approximately 2 to 15 mm because this diameter range represents a reasonable size for the use of the device disclosed in Fallwell et al.

In re Rose , 220 F.2d 459, 105 USPQ 237 (CCPA 1955) (Claims directed to a lumber package "of appreciable size and weight requiring handling by a lift truck" where held unpatentable over prior art lumber packages which could be lifted by hand because

Art Unit: 3762

limitations relating to the size of the package were not sufficient to patentably distinguish over the prior art.); In re Rinehart, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976) ("mere scaling up of a prior art process capable of being scaled up, if such were the case, would not establish patentability in a claim to an old process so scaled." 531 F.2d at 1053, 189 USPQ at 148.). In Gardner v. TEC Systems, Inc., 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George Manuel whose telephone number is (571) 272-4952.

/George Manuel/  
George Manuel  
Primary Examiner  
Art Unit: 3762